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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,465	11/13/2003	Peter Madsen	6258.210-US	9421

23650 7590 02/07/2006

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EXAMINER	
STOCKTON, LAURA LYNNE	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,465	MADSEN ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/996,023.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/13/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending in the application.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/996,023, filed on November 16, 2001.

Information Disclosure Statement

The non-US Patent references listed on the 1449 Form filed December 13, 2003 could not be considered because the parent application, which Applicants' have stated contains copies of the references, no longer contained these references.

It is suggested that Applicants file copies of each of these non-US Patent references when responding to this Office Action.

Claim Objections

Claims 1-16 are objected to because of the following informalities:

a) in claim 1 (page 60), "sulfonyl" is misspelled in the last three compounds listed;

b) in claim 1 (page 65), "fluoro" is misspelled in the second and third compounds listed, etc.

It is suggested that Applicants check the spelling of each of the compounds listed in the claims.

Further, it is suggested that Applicants add commas or semi-colons after each compound.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759

F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 87, 88 and 91 of copending Application No. 10/980,199. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims in 10/980,199 differ only by generic description. See, for example, the fourth compound listed on page 505, right column, in 10/980,199.

The indiscriminate selection of "some" among "many" is *prima facie* obvious. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., a glucagon antagonist). One skilled in the art would thus be motivated to prepare compounds embraced by 10/980,199 to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating, for example, obesity. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 57-67 of U.S. Patent No. 6,875,760 (see, for example, the first compound in columns 507-508 and claim 63) and claims 52-56 of U.S. Patent No. 6,503,949 (see, for example, the third compound in columns 501-502 and claim 56). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed invention and the claims in the patents differ only by generic description of the products being administered.

The indiscriminate selection of "some" among "many" is *prima facie* obvious. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., a glucagon antagonist). One skilled in the art would thus be motivated to prepare compounds embraced by each of the patents to arrive at the

instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating, for example, obesity. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Lau et al. {U.S. Pat. 6,503,949}.

Lau et al. disclose methods of using products that are the same as some of the products instantly claimed. See, for instance, the third compound in columns 501-502 of Lau et al and the methods disclosed in column 40, lines 46-67.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. {U.S. Pat. 6,503,949}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim methods of using glucagon antagonists. Lau et al. teach glucagon antagonists, that are either structurally the same as (see above 102 rejection) or structurally similar to the Applicants' glucagons antagonists, which are useful in treating hyperglycemia, diabetes, obesity, etc.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between some of the teachings in Lau et al. and the present claimed invention is that some of the specie listed for the methods in the instant claims are generically described in Lau et al.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious. The motivation to make the claimed compounds derives from the expectation that

structurally similar compounds would possess similar activity (e.g., a glucagon antagonist).

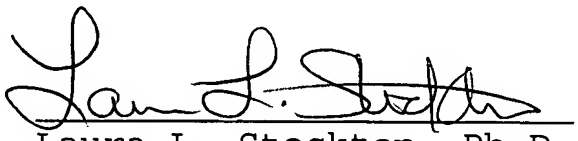
One skilled in the art would thus be motivated to prepare compounds embraced by Lau et al. to arrive at the compounds being administered for the instant methods of use with the expectation of obtaining additional beneficial compounds which would have glucagons antagonist properties and would be useful in treating, for example, hyperglycemia, diabetes, obesity, etc. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information

Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



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Art Unit 1626, Group 1620
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February 6, 2006